K030548

APR 0 4 2003

510(k) Summary

Submitter Information:

St. Shine Optical Co., Ltd.
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Hsi Chih City, 221 Taipei Hsein
Taiwan R.O.C.

Contact Person:

Garold L. Edwards, O.D., F.A.A.O.
Regulatory Consultant
2091 Upper Scenic Drive
Felton, California 95018

Telephone: (408) 221-3860
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Date Prepared: February 7, 2003

Device Name:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Names:	Saview Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Classification Name:	Soft (Hydrophilic) Contact Lens
Device Classification:	Class II (21 CFR 886.5925)

Predicate Devices:

The Saview 55 F (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear, the Saview Toric 55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear and the PolyVue Unisoft (methafilcon A) Soft (hydrophilic) Multifocal Contact Lens for Daily Wear were selected as the predicate devices.

The Saview 55 Multifocal lenses will be manufactured and sterilized at the same manufacturing site, using identical moulding, sterilization and packaging processes as the Saview 55 F and the Saview Toric 55.

Description of Devices:

The Saview 55 Multifocal (methafilcon A) Soft (hydrophilic) Daily Wear Contact Lens is a hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera. The Saview 55 Multifocal Contact Lens is available in an aspheric lens design. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate, methacrylic acid and diethlene glycol monomethacrylate, crosslinked with ethylene glycol dimethacrylate. The lens contains 55% water by weight. The lens is tinted using Pigment Blue 15.

Comparison to Predicate Device

Device *510(k) Number*	**Saview 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens**	**Saview 55F and Saview Toric 55 (methafilcon A) Soft (hydrophilic) Contact Lenses** **K020917 K021295**	**PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical and Toric Soft (hydrophilic) Contact Lens** **K980818**
Material	methafilcon A	methafilcon A	methafilcon A
Material classification	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4
Indication for use	myopia, hyperopia and presbyopia	myopia, hyperopia and astigmatism	myopia, hyperopia, astigmatism and presbyopia
Water content	55%	55%	55%
Visible light transmittance	97.6%	97.6%	> 95%
Dk (35° C)	19.5×10^{-11}	19.5×10^{-11}	18.83×10^{-11}
Powers	+12.00 to -20.00 Diopters; continuous add power to +3.25	+12.00 to -20.00 Diopters	+20.00 to –20.00 Diopters; continuous add power to +3.25
Color	blue visibility	blue visibility	clear or green visibility
Refractive index	1.3974 (wet)	1.3974	1.415
Method of manufacture	Moulded	Moulded	Lathe cut

Indications for Use:

The **Saview Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

Discussion of Safety and Substantial Equivalence:

Information submitted in the 510(k) establishes that the **Saview 55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens** has physicochemical properties comparable to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date.

Conclusion:

The devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 4 2003

St. Shine Optical Co., Ltd.
c/o Garold L. Edwards
Regulatory Consultant
2091 Upper Scenic Drive
Felton, CA 95018

Re: K030548
Trade/Device Name: Saview 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: February 7, 2003
Received: February 20, 2003

Dear Mr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS STATEMENT

Device Names:

Saview 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use:

The **Saview 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use

Daniel W. C. Brown, P4.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K030548